

REMARKS*Amendments to the Specification*

The Specification has been amended to add reference to the appropriate SEQ ID NO. to the sequence contained in Fig. 4. No new matter has been added.

Claim Amendments

Claims 32 and 42 have been amended to delete the recitation of “Type II” added in a prior amendment.

Claims 32 and 42 have also been amended to clarify that the dual cleavage restriction enzyme is capable of cleaving said nucleotide sequence once upstream of said recognition site and once downstream of said recognition site and excising from said vector a restriction fragment which includes said recognition site, i.e., to clarify that the recitation describes the nature of the dual cleavage restriction enzyme for which the recognition site is contained in the claimed vector and not a process limitation.

Claim 39 has been amended to delete the recitation “such that digestion with BaeI excises from said vector a restriction fragment which includes said recognition site and forms insertion sites in said vector” to remove the alleged process limitations from the claim.

Claim 41 has been amended to clarify that the recitation is a property of the dual cleavage restriction enzyme and not a process limitation.

Claim 42 has been amended to delete the recitation “between two insertion sites, wherein said two insertion sites are formed by digestion with a single Type II double cleavage restriction enzyme capable of cleaving said nucleotide sequence once upstream of the recognition site of said restriction enzyme and once downstream of said recognition site to excise from said vector a restriction fragment that contains the recognition site for said restriction enzyme, and wherein said insertion cassette comprises” to remove alleged process limitations from the claim.

Claims 40, 49, 50 and 51 have been cancelled.

No new matter has been added.

Compliance With Sequence Rules

Applicants are submitting herewith a Substitute Sequence Listing in paper and computer readable form addressing the issues identified in the Notice to Comply mailed with the Office Action. In addition, the description of Fig. 4 of the application has been amended herein to add reference to the appropriate SEQ ID NO.

Rejection of Claim 32-35, 39-46, and 48-51 under 35 U.S.C. § 112, First Paragraph

Claims 32-35, 39-46 and 48-51 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner has requested that Applicants specifically identify support for the claim amendments presented in the Amendment mailed to the U.S. Patent & Trademark Office on February 2, 2009.

Claim 32 has previously been amended to recite “the snRNA-encoding portion” and “capable of cleaving said nucleotide sequence once upstream of said recognition site and once downstream of said recognition site.” Support for these amendments can be found throughout the specification, for example, at paragraph 0048 and Fig. 4, and at paragraph 0057, respectively, of the published application.

Claim 39 has previously been amended to independent form. Support for the amendment can be found throughout the specification, for example, at paragraph 0059 of the published application.

Claim 42 has previously been amended to recite “the snRNA-encoding portion” and “capable of cleaving said nucleotide sequence once upstream of said recognition site and once downstream of said recognition site.” Support for these amendments can be found throughout the specification, for example, at paragraph 0048 and Fig. 4, and at paragraph 0057, respectively, of the published application.

Claim 49 has previously been amended to independent form. Support for the amendment can be found throughout the specification, for example, at paragraph 0059 of the published application.

The prior amendment to add “Type II” to claims 32 and 42 is reversed herein.

No new matter has been added as a result of these amendments. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claims 32-35, 39-46 and 48-51 Under 35 U.S.C. §112, Second Paragraph

Claims 32-35, 39-46 and 48-51 are rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner comments that one of skill in the art would not be able to determine the scope of the presently claims invention because of reference to an intermediate vector and process limitations.

The claims have been amended to remove certain alleged process limitations, as well as to clarify that other recitations describe the nature of the dual cleavage restriction enzyme for which the recognition site is contained in the claimed vector (and are not a process limitations). Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claims 32-35, 39-46 and 48-51 under 35 U.S.C. § 103(a)

Claims 32-35, 39-46 and 48-51 are rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Noonberg *et al.* (Patent 5,624,803); Halle *et al.* (Patent 6,303,308); and Abounader *et al.*, Design and Expression of Chimeric U1/Ribozyme Transgenes, *Methods in Molecular Biology* 252: 209-219.

The Examiner alleges that Noonberg *et al.* teaches vectors comprising a U6 snRNA promoter, a stabilizing region from which a hairpin-forming sequence can be transcribed, a nucleotide sequence of interest, and a termination sequence wherein the stabilizing region is a sequence encoding a U6 snRNA. The Examiner further states that Noonberg *et al.* teaches that any restriction endonuclease can be utilized as long as two cleavage sites are present. The Examiner concedes that Noonberg *et al.* does not teach a dual cleavage restriction enzyme or a U1 snRNA but alleges that these elements are disclosed by Halle *et al.* and Aboundader *et al.*, respectively. The Examiner states that the invention would have been obvious to one of ordinary skill in the art because the substitution of one known element for another would have yielded predictable results.

Applicants respectfully traverse the rejection. Noonberg *et al.* does not teach or suggest, *inter alia*, vectors comprising an isolated nucleotide sequence encoding an snRNA. Noonberg *et al.* merely disclose vectors which comprise a U6 snRNA promoter sequence, not a nucleotide sequence actually encoding U6 snRNA; this defect is not remedied by Halle *et al.* or Abounader *et al.* Accordingly, even combination with Halle *et al.* and Abounader *et al.* does not render obvious the claimed invention, as the combination fails to teach or suggest all elements of the claimed invention. Reconsideration and withdrawal of the rejection are respectfully requested.

Prior Rejections Under 35 U.S.C. §112

Applicants comment here for the record with regard to the rejections previously made under 35 U.S.C. §112 in light of Applicants' removal of the recitation of "Type II" in the claims presented herein. Applicants respectfully submit that the recognition site for BaeI is but one example of a suitable restriction enzyme recognition site within the more broadly described invention. BaeI is representative of the class of enzymes that cleave on both sides of the recognition sequence; there are many other well-defined members of this class known to the skilled artisan (e.g., A1oI, BpII, Bst44I, BcgI, BsaXI, Bsp24I, CjeI, CjePI, HaeIV, Hin4I and PpiI). Having described this aspect of the invention both broadly (i.e., use of a recognition site for a dual cleavage restriction enzyme capable of cleaving once upstream and once downstream of the recognition site, such that digestion with a single restriction enzyme excises from the vector a restriction fragment which includes the recognition site and forms insertion sites in the vector) and narrowly (i.e., BaeI as an exemplary restriction enzyme), Applicants must be considered to have been in possession of the invention as claimed at the time the application was filed and to have enabled said invention. Removal of the recitation of "Type II" does not alter this conclusion, as this recitation was redundant in view of the functional language of the claims.

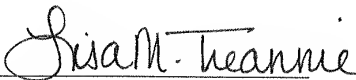
CONCLUSION

In view of the above remarks and amendments, Applicants respectfully submit that the application is in condition for allowance. If the Examiner believes that a telephone call would be useful in expediting the allowance of the application, the Examiner is invited to contact the undersigned.

Applicant believes that no fee is due for the response other than the fees provided for on the accompanying transmittal. However, if an additional fee is due, please charge Deposit Account No. 50-3655, from which the undersigned is authorized to draw, under order number WIBR-523-101.

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Respectfully submitted,

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